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Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-15 EUR-12 EA-12 NEA-10 ISO-00 OES-09
SIG-03 /068 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
ARA/ECA: SPMYLES
ARA/CEN:JDAVIS EA/RIMBS:MEASTON
ARA/AND/E:MGUERRA
EA/K:DBLAKEMORE
NEA/IRN:MGREENE
EUR/CE:SKLINGAMAN
EUR/NE:HWOOLFLEY
----------118798 131713Z /47
P 131604Z SEP 78
FM SECSTATE WASHDC
TO AMCONSUL RIO DE JANEIRO PRIORITY
AMCONSUL SAO PAULO PRIORITY
AMEMBASSY SAN JOSE PRIORITY
AMEMBASSY QUITO PRIORITY
AMEMBASSY SEOUL PRIORITY
AMEMBASSY TEHRAN PRIORITY
AMEMBASSY BONN PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY SINGAPORE PRIORITY
INFO AMEMBASSY BRASILIA PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, BR, CS, EC, KS, IR, GW, UK,

SUBJECT: FDA ADVISORY - FIRM INITIATED RECALL OF KIDNEY
DIALYSIS BLOOD SETS (RECALL T-316/317-8)
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1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL:
PRODUCT INVOLVED - ELEVEN CATALOG NUMBERS OF KIDNEY DIALYSIS
BLOOD SETS

A. T-316-8 INLET (ARTERIAL) BLOOD SETS - SIX CATALOG NUMBERS
1. 5M1635 - WITH SALINE PORT WITH MONITORING LINE

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2. 5M1636 - WITHOUT SALINE PORT WITH MONITORING LINE
3. 5M1642 - WITH POST-PUMP PRESSURE MONITORING CHAMBER AND SINGLE PUMP SEGMENT.
4. 5M1680 - WITH POST-PUMP PRESSURE MONITORING CHAMBER WITH SALINE POSTS
5. 5M1686 - WITHOUT SALINE PORT WITHOUT MONITORING LINE
6. 5M1689 - WITH POST-PUMP PRESSURE MONITORING CHAMBER WITH SALINE PORT AND LEVEL ADJUSTMENT ARM.

B. T-317-8 OUTLET (VENOUS) BLOOD SETS - FIVE CATALOG NUMBERS
1. 5M1641 - WITH FILTER, 5 FT. MONITORING LINE WITH LUER CONNECTOR AND "T" INJECTION SITES
2. 5M1655 - WITH FILTER AND "T" INJECTION SITES
3. 5M1681 - WITH FILTER WITH MONITORING LINE

4. 5M1682 - WITH FILTER WITH MONITORING LINE AND LEVEL ADJUSTMENT ARM
5. 5M1683 - WITH FILTER WITHOUT MONITORING LINE
SETS ARE PACKED IN UNIT CARTONS, 12 CARTONS PER CASE

2. PRODUCT IDENTIFICATION:
A. T-316-8 INLET (ARTERIAL) SETS

(1) 5M1635 - LOT NOS. H263F9
H263H4, H263L4, H263N0, H263L0, H263L7, H263R8

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(2) 5M1636 - LOT NO. H263P0

(3) 5M1642 - LOT NOS. ZC13757
ZC138S8, ZC138SP, ZC138X0, ZC139P6

(4) 5M1680 - LOT NO. S17F2

(5) 5M1686 - LOT NO. S14N6

(6) 5M1689 - LOT NO. H262L0

B. T-317-8 OUTLET (VENOUS) SETS

(1) 5M1641 - LOT NOS. ZC138X8, ZC138X9

(2) 5M1641 - LOT NOS. ZC137X8, ZC138F6, ZC138F8, ZC138L4, ZC138L6, ZC138F5, ZC138F7, ZC138F9, ZC138L5, ZC138L7

(3) 5M1681 - LOT NO. S16P4

(4) 5M1682 - LOT NOS. ZC140L7, ZC140L9

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(5) 5M1683 - LOT NO. S14H5

3. MANUFACTURER: INJECTION SITE MFR: TRAVENOL LABORATORIES, INC., ROUND LAKE, IL.
SET ASSEMBLER: TRAVENOL LABORATORIES, INC., MOUNTAIN HOME ARK.;
TRAVENOL LABORTORIES, INC. JAYAYA, PUERTO RICO

4. RECALLING FIRM: TRAVENOL LABORATORIES, INC., ARTIFICIAL ORGANS DIVISION, ONE BAXTER PARKWAY, DEERFIELD, IL 60015

5. REASON FOR RECALL: ALCOHOL USED AS A BACTERIOCIDAL AGENT ON THE PLASTIC INJECTION SITES OF THESE SETS REACTS
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CHEMICALLY WITH THE PLASTIC RETAINERS WHICH HOLD THE RUBBER DIAPHRAM FOR NEEDLE INSERTION. USE OF ALCOHOL

HAS CAUSED FRACTURING OF THE PLASTIC RETAINERS AND HAS RESULTED IN A LOSS OF BLOOD TO DIALYSIS PATIENTS. INJEC-TION SITES ARE ULTRASONICALLY WELDED TO PORTS ON THE DIALYSIS TUBING AND SUBJECTED TO EITHER POSITIVE AND NEGATIVE PRESSURE DURING THE DIALYSIS PROCEDURE. IN NOVEMBER, I977, THESE SETS AND INVOLVED LOTS NUMBERS UNDERWENT A FORMULATION CHANGE FOR THE PLASTIC RETAINER FROM A PHTALATE FORMULATION TO PLEXIGLASS FORMULATION. THE FIRM'S INITIAL TESTING OF THE NEW FORMULATION DID NOT DETECT THE PROBLEM. ADDITIONAL TESTING AFTER THE RECEIPT OF FIVE COMPLAINTS BETWEEN 4/8/78 AND 6/8/78 VERIFIED CRACKING OF SITES AFTER ONE OR MORE WIPING WITH ALCOHOL AND AN INCREASE INCIDENCE OF FAILURE OVER A PERIOD OF TIME.

6. THE FIRM INITIATED A RECALL OF THE INVOLVED CATALOG NUMBERS AND LOT NUMBERS ON 6/16/78 BY SENDING A CERTIFIED LETTER, RETURN RECEIPT REQUESTED, TO ALL HOME PATIENTS, SERVIPAK CUSTOMERS, DIALYSIS UNIT DIRECTORS, AND DIALYSIS UNIT ADMINISTRATORS. LETTER ADVISED USING ONLY BETADINE (POVIDONE-IODINE) SOLUTION TO WIPE THE INJECTION SITES AND STATED "DO NOT USE ALCOHOL". THE FIRM NOTIFIED FDA OF THEIR ACTIONS BY PHONE AND LETTER ON 6/19/78. THE FIRM PLANS TO PLACE WARNING LABELS WITH THESE SAME INSTRUCTIONS ON ALL UNITS UNRELEASED OR ON HOLD AT DISTRIBUTION CENTERS.

7. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN ADVISED BY FIRM OF NCECSSARY ACTION. ANY QUESTIONS CONSIGNEES MAY HAVE
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REGARDING RECALL SHOULD BE REFERRED TO FIRM.

8. FOREIGN CONSIGNEES AS SUPPLIED TO FDA BY FIRM ARE
AS FOLLOWS:

UNIVERSIDADE FEDERAL DO RIO DE JANEIRO, CICADE UNIVERSITARIA
IIHA FUND, RIO DE JANEIRO BRAZIL

CENTRAL DISTRIBUIDORA, INDUSTRIAL SA, APARTADO NO 10256,
SAN JOSE, COSTA RICA

HOSPITAL MILITAR, LADRON DE GUEVARA, QUITO, ECUADOR

UON SEI UNIVERSITY, SEOUL, KOREA

SA'ID TABIBI AND CO., P.O. BOX 14/1551, TEHRAN, IRAN

TRAVENOL PRODUTOS HOSPITALARES, JARDIM PAULISTA, RUA
SUZANO 73 CEP 01435, SAO PAULO, BRAZIL

TRAVENOL GMBH, NYMPHENBURGER STRASSE 1, POSTFACH 202429
D-8000, MUENCHEN 2 GERMANY

TRAVENOL LABORATORIES, LTD., CAXTON WAY THETFORD,
NORFOLK, ENGLAND

TRAVENOL MFG. PTE. LTD., 300 SERANGOON RD., SINGAPORE 8 CHRISTOPHER

NNN

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: n/a
Control Number: n/a
Copy: SINGLE
Draft Date: 13 sep 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE231819
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
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From: STATE
Handling Restrictions: n/a
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Legacy Key: link1978/newtext/t19780970/aaaacgek.tel
Line Count: 202
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Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 9cf45751-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1449076
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - FIRM INITIATED RECALL OF KIDNEY DIALYSIS BLOOD SETS (RECALL T-316/317-8) UNCLASSIFIED
TAGS: OGEN, ETRD, EIND, TBIO, BR, CS, EC, KS, IR, GE, UK
To: RIO DE JANEIRO SAO PAULO MULTIPLE
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/9cf45751-c288-dd11-92da-001cc4696bcc
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